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| 10/667,909 | 09/22/2003 | Richard F. Murphy | 1001.1530101 | 9920 |

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| EXAMINER |
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KOHARSKI, CHRISTOPHER

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| ART UNIT | PAPER NUMBER |
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3763

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09/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--|---|--|
| Office Action Summary | Application No. 10/667,909 | Applicant(s) MURPHY, RICHARD F. | |
| | Examiner CHRISTOPHER D. KOHARSKI | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/11/2009 has been entered.

Acknowledgements

The Examiner acknowledges the reply filed 08/11/2009 in which claims 41, 48, and 53-54 were amended and new claims 57-58 were added. Currently claims 41-58 are pending for examination in this application.

Claim Objections

Claims 41 and 57 is objected to because of the following informalities: Regarding claims 41 and 57, the claims each contain a grammatical error, "...one of more metallic filamentsg..."(claim 41), "...wherein the diameter of each of the plurality of metallic filaments is constant..."(claim 57). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 41, 48, 53 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claims 41, 48, 53 and 57, the amendments lack support in the specification or drawings. For example, the disclosure does not disclose "...the portion having a constant length..." or "...the portion including a majority of the surface area of the filament..." or "...the plurality is constant along the portion subsequent to the treating step...".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 41 is rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (5,330,521). Cohen discloses a low resistance implantable electrical lead.

Regarding claim 41, Cohen discloses a medical device (12) (Figure 4) including a reinforcing member (42) providing one or more filaments (42) adapted and configured to be made into the reinforcing member for the medical device, the one or more filaments including a metallic surface (col 8, ln 20-30) having an initial surface area, treating at least the portion (section of filament near dL, i.e. a single wire coil turn, or any finite point of the surface of the filament) having a constant profile of the surface (col 9, ln 30-

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45) to provide a final surface area that is greater than the initial surface area (i.e. removal of oxides and films, which were covering the surface are, this removal of these elements increases the surface area), and creating the reinforcing member using the one or more metallic filaments and incorporating the member into a medical device (12) (Figures 1-7, cols 1-3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 41-53 and 55-56 are rejected under 35 U.S.C 103(a) as being unpatentable over Parisi et al. (US2001/0027310) in view of Cohen (5,330,521). Parisi et al. discloses a guide catheter with a lubricous inner liner.

Regarding claims 41-56, Parisi et al. discloses guide catheter (11) with an inner liner and the device being a multi-material layered composite structure. Parisi et al. discloses a catheter comprising a braided (14) metallic filament-reinforcing member (30,

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[0034]), an inner (16) and outer surface (12) with a lumen extending there through (13).

The outer layer and inner layer of the catheter are composed of polymeric materials ([0028]) connected to the metal reinforcing element (Figures 1-7, [0002-0013]). Parisi et al. meets the claim limitations as described above but does not include a metallic member that is etched to provide a difference in surface area as claimed.

However, Cohen teaches a low resistance implantable electrical lead cable.

Regarding claims 41-53 and 55-56, Cohen teaches a medical device (Figure 2) with a polymeric outer layer outer layer (26, 43), a reinforcement metal filament (22, 42), and a conductive coating layer. Cohen discloses that the metal reinforcement core (22, 42) is chemically etched before the application of a subsequent material layer (col 6, ln 35-65, col 9, ln 30-45) (Figures 3-4).

At the time of the invention, it would have been obvious to use the teachings of Cohen to etch the metal filament of Parisi et al. because it is well known that the etching can be used to clean the material before use and is used to increase adhesion between layers and different materials of a medical device. The references are analogous in the medical device art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Cohen (col 6, ln 50-70).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 41-53 and 55-56 are rejected under 35 U.S.C 103(a) as being unpatentable over Parisi et al. (US2001/027310) in view of Bates et al.

(US2002/009278). Parisi et al. discloses a guide catheter with a lubricous inner liner.

Regarding claims 41-53 and 55-56, Parisi et al. discloses guide catheter (11) with an inner liner and the device being a multi-material layered composite structure. Parisi et al. discloses a catheter comprising a braided (14) metallic filament-reinforcing member (30, [0034]), an inner (16) and outer surface (12) with a lumen extending there through (13). The outer layer and inner layer of the catheter are composed of polymeric materials ([0028]) connected to the metal reinforcing element (Figures 1-7, [0002-0013]).

Parisi et al. meets the claim limitations as described above but does not include a metallic member that is etched to provide a difference in surface area as claimed.

However, Bates et al. teaches a coated implantable medical device.

Regarding claims 41-53 and 55-56, Bates et al. teaches a medical device (10, Figure 1) with an assembly component (14) that is abraded and roughened to increase the surface roughness for subsequent coating processes ([0022-0029]).

At the time of the invention, it would have been obvious to use the teachings of Bates et al. to abrade the metal filament of Parsi et al. because it is well known that the abrasion can be used to clean the material before use and is used to increase adhesion between layers and different materials of a medical device. The references are analogous in the medical device art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Bates et al. ([0011-0013]).

Claim Rejections - 35 USC § 103

Claim 54 is rejected under 35 U.S.C 103(a) as being unpatentable over Parisi et al. (US2001/027310) in view of Bates et al. (US2002/009278) in further view of Lee et al. (USPN6,464,889). The modified Parisi et al. meets the claim limitations as described above except for the chemical etching process.

However, Lee et al. teaches a surface modification of medical implants.

Regarding claim 54, Lee et al. teaches that there are several comparable methods for surface treatment including chemical etching and surface abrasion (col 2, ln 1-25).

At the time of the invention, it would have been obvious to use the chemical etching process as taught by Lee et al. with the modified system of Parisi et al. because they are equivalent surface treatment procedures. The references are analogous in the

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art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Lee et al. (cols 1-2).

Response to Arguments

Applicant's arguments filed 08/11/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that references Parisi et al. (US2001/0027310) and Cohen (5,330,521) do not disclose the scope of the amended claims, specifically "...treating at least the portion of the surface of the one or more metallic filaments to provide a final surface area that is greater than the initial surface area.", and does not disclose "... a portion of the surface to be treated...".

The Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

The Examiner asserts that the Parisi et al. and Cohen references meet the claim limitations as disclosed above. Regarding the Cohen reference, the limitations of the claim are extremely broad and will interpreted as such. The mere claim of an increase of surface area has many possible interpretations that the Cohen reference meets. For example, the wire core (42) is covered with oxides and films prior to treatment, thus having a lower surface area available and after treatment having an increased surface area since these oxides and films are removed. Additionally, the claimed "portion" can be construed as any finite surface of the Cohen metal wire core, thusly any portion can

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be considered when describing the treated areas of the wire core and meet the claim limitations of having a constant profile/length (see rejection above).

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763